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EXAMINER	
MAKI, S	
ART UNIT	PAPER NUMBER
1733	11

DATE MAILED: 04/03/98

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

a) ☒ is extended to run _____ or continues to run 3 months from the date of the final rejection

b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition , and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☒ Applicant's response to the final rejection, filed 3-9-98 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☐ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:

   a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.

   b. ☐ They raise new issues that would require further consideration and/or search. (See Note).

   c. ☐ They raise the issue of new matter. (See Note).

   d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

   e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: _____

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ Upon the filing an appeal, the proposed amendment ☒ will be entered ☐ will not be entered and the status of the claims will be as follows:

   Claims allowed: _____
   Claims objected to: _____
   Claims rejected: 15-17, 20-22 and 23, 24, 26-29 (as directed to species #1)

   However;

   ☒ Applicant's response has overcome the following rejection(s): the 112 second paragraph rejection against claim 25 and regarding "the material parts"

4. ☒ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because _____
   See ADVISORY ACTION ATTACHMENT

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficent reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☐ Other

*U.S. GPO: 1997-417-381/62704

ADVISORY ACTION ATTACHMENT

With respect to the 112 second paragraph rejection against claims 23-29 applicant asserts that these claims relate solely to elected species #1 and that 35 USC 112 second paragraph would provide no basis for rejecting claims even if drawn to non-elected species. The examiner disagrees. FIRST: The examiner maintains his position that claims 23-29 are directed to species #2 instead of species #1. SECOND: 35 USC 112 second is a proper basis for rejecting claims which are not directed to elected subject matter. See MPEP 821 ("Because applicant believes the claims are readable on the elected invention and the examiner disagrees, the metes and bounds of the claim(s) cannot be readily ascertained, rendering the claim(s) vague and indefinite within the meaning of 35 USC 112, second paragraph").

With respect to the 112 first paragraph rejection regarding, "radially expanding at least the portion of the stent in the tube or allowing at least the portion of the stent to expand in the tube" (emphasis added), applicant responds by (1) referring to page 2 line 33 to page 3 line 1, page 5 lines 2-5 and page 6 line 27 and (2) asserts "One skilled in the art will appreciate that balloon expandable stents may be expanded by balloons"; applicant noting that literal support is not required and that applicant

need not describe the conventional. In response, the examiner makes the following comments: FIRST: the portions of the specification cited by applicant (page 2 line 33 to page 3 line 1, page 5 lines 2-5 and page 6 line 27) are consistent with "allowing at least the portion of the stent to expand in the tube" (which is supported by the original disclosure) but fail to describe / reasonably convey radially expanding at least the portion of the stent in the tube instead of allowing at least the portion of the stent to expand in the tube. SECOND: The examiner agrees that literal support is not required. However, in addition to not providing literal support, the original disclosure fails to reasonably convey to one of ordinary skill in the art that applicant had possession of the concept of what is now claimed. The examiner also agrees that the application need not describe the conventional. However, the lack of a requirement to describe conventional subject matter does not allow applicant to claim conventional subject matter which was not described.

With respect to the 112 first paragraph rejection regarding claims 23, 24 and 26-29, applicant asserts that support for claims 23-29 is found throughout the specification at for example page 2 line 20 to page 3 line 1; at page 3 lines 19-28; and in

figures 1 and 2. The examiner disagrees. Page 3 lines 19-28 and figures 1 and 2 are describing species #2 instead of species #1. The specification clearly teaches that covering layer (3) in figures 1 and 2 was formed (a) using a tube having a lifting medium (7) in order to avoid adherence to elastomeric composition forming the covering layer and (b) wetting the stent with elastomeric polymerisable composition dissolved in a sufficient amount of solvent to permit wet forming of a continuous covering layer around the totality of the discontinuous wall of the stent formed by the wire mesh inside of the tube (6). These steps of using a tube having a lifting medium which prevents adhesion and wet forming of a covering layer (insitu formation of a covering layer on a stent) are directed to species #2 instead of species #1 which inserts the stent into a preformed tube and which bonds the stent to the tube for example by using an adhesive. Page 3 lines 19-28 and figures 1 and 2 describe and show wet forming a covering layer on a stent such that material of the wet formed covering layer covers the wires of the of the stent as shown in figures 1 and 2 but **fails** to describe bonding a stent to a tube with adhesive such that material of the tube moves past the adhesive and covers the wires of the stent. As to page 2 line 20 to page 3 line 1, this disclosure describes a connection being

formed which one of ordinary skill in the art would understand as either being formed by coating as described at page 2 line 34, page 3 lines 19-28 and figures 1 and 2 or by inserting a stent into a tube and bonding the stent to the tube as described for example at page 6 lines 10-22. Page 2 line 20 to page 3 line 1 fails to describe shaping the covering layer into an outer cylindrical surface without irregularities with the shaped material surrounding the discontinuous wall from the outside and extending radially within the discontinuous wall and forming an inner surface following in distance material parts of the discontinuous wall in places with material parts and following the cylindrical outer surface in places without material parts thereby forming an inner surface with irregularities as set forth in claims 23, 24 and 26-29 when inserting a stent into a tube and bonding the stent to the tube.

As to the 112 first paragraph rejection regarding enablement, applicant again refers to page 2 line 20 to page 3 line 1; at page 3 lines 19-28; and in figures 1 and 2. These portions of the specification provide enablement for shaping covering material which was formed in situ on the stent by a wet forming technique but fail to enable how to shape the covering

material when a tube **instead of** a wet formed covering material as in claims 15-22 is used.

With respect to the 103 rejection, applicant argues and the examiner agrees that the stent of MacGregor is an open structure. However, Gianturco (a reference ignored by applicant and relied upon by the examiner for the suggestion to provide a sleeve on a stent) teaches that providing a sleeve on a stent prevents a tumor from growing between the struts of the stent thus avoiding restenosis and affording a longer term solution than that possible with conventional wire stents. Gianturco's teaching to provide a stent with a preformed sleeve, therefore, constitutes ample motivation to provide a stent with a sleeve instead of an open structure; it being noted that applicant has offered no reason why the disclosure of MacGregor at column 5 lines 44-50 teaches that integration of a stent with a tumor is desirable. Also note Simon's teaching that by providing a sleeve on a stent that the sleeve can advantageously be a graft and operate to provide a new passageway wall when required.

With respect to the 103 rejection applicant asserts and the examiner agrees that Kaster relates to a graft. The examiner adds that a "sleeve stent is essentially a graft". See Simon at column 4 lines 52-54.

Applicant requests an examiner's affidavit because applicant asserts that the examiner has alleged that most of the steps are known or conventional and that such steps are known in a combination which corresponds to the claimed invention. In response, the examiner notes the following:

FIRST: In the office action, the examiner took official notice of three separate facts:

(1) "curable adhesive medium" which is cured to effect bonding is a well known/conventional type of adhesive in the bonding art;

(2) "elastomeric composition dissolved in solvent" is a well known/conventional type of adhesive in the bonding art;

(3) bonding a first tubular member to another tubular member by coating the inside of the first tubular member with adhesive and then inserting the second tubular member into the first tubular member is well known / conventional in the bonding art. The examiner is permitted to take official notice of facts. See MPEP 2144.03.

SECOND: The examiner has not asserted that most of the steps are known or conventional since the examiner has relied on the applied and cited prior art as evidence to show:

(1) providing a preformed sleeve (Gianturco);

(2) providing a stent (MacGregor, Gianturco);

(3) positioning the stent such that it is inserted in the sleeve (Gianturco);

(4) bonding the stent and sleeve together (Gianturco, Kaster);

(5) using adhesive (Gianturco);

(6) bonding the stent to the inner surface of the sleeve (Gianturco, Kaster);

(7) compressing the stent and expanding the stent to facilitate insertion (MacGregor).

The three separate facts of which examiner took official notice were not used to show any of the above limitations /steps in claims.

THIRD: the examiner has not asserted that most of the steps are known in a combination which corresponds to the claimed invention. The examiner did not assert that any of the three separate facts are known in the stent art. Instead, the examiner asserted that the three separate facts were known in the bonding art in general - that portion of the bonding art outside of the stent art. Also, the examiner did not assert that these separate facts are known in combination. Each fact was asserted

separately so as to make it clear that the examiner was asserting only that each fact was individual known per se.

FOURTH: As noted above, the examiner took each separate fact as being known per se. With respect to the facts relating to the adhesive: the motivation to use an adhesive comes not from the facts supported by official notice but from the applied and cited prior art (Gianturco). With respect to the fact relating to coating adhesive on the inside surface of a tube, the motivation to use an adhesive to bond a stent and a tube (sleeve) together and to bond the stent to the inside surface of the tube comes not from the fact supported by official notice but from the applied and cited prior art (Gianturco and Kaster).

FIFTH: Since applicant's request for an affidavit is based on an incorrect interpretation of the scope of the three separate facts (the facts being asserted by the examiner as known per se instead of known the stent art or combination of the steps set forth in the claims), an affidavit is unnecessary. However, if the examiner has misinterpreted applicant's request, applicant should specifically challenge each of the three assertions by the examiner. For example, applicant could assert that a curable adhesive medium is not known per se and accordingly challenge the examiner's assertion that a curable adhesive medium is known per

se and request evidence in the form of patents or textbooks to support the assertion that a curable adhesive medium is known per se.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven D. Maki whose telephone number is (703) 308-2068. The examiner can normally be reached on Monday to Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Ball, can be reached on (703) 308-2058. The fax phone number for Art Unit 1733 is (703) 305-7718. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0661.

STEVEN D. MAKI 4-3-98
PRIMARY EXAMINER
GROUP 1300

Steven D. Maki
April 3, 1998